

Attorney Docket No.: DRE-0055
Inventors: Laurencin et al.
Serial No.: 09/878,641
Filing Date: June 11, 2001
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REMARKS

Claims 1-11 are pending in the instant application.
Claims 1-11 have been rejected. Reconsideration is respectfully requested in light of the following remarks.

Rejection of Claims 1-11 under 35 U.S.C. § 103(a)

Claims 1-3 and 6-9 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Wolowacz et al. (WO 95/01810 A1) in view of Chervitz (U.S. Patent 4,917,699).

Claims 4, 5, 10 and 11 have also been rejected under 35 U.S.C. § 103(a) as being unpatentable over Wolowacz et al. in view of Chervitz as applied to claims 2 and 8, and further in view of Vacanti (U.S. Patent 5,855,610).

Arguments presented by Applicants in the response filed January 5, 2005 were deemed unpersuasive by the Examiner. In particular, the Examiner suggests that Applicants have not provided any evidence showing that there was no reasonable expectation of success that the three-dimensional braiding technique of Chervitz of polyester yarns could be performed successfully with degradable, porous, polymeric fibers in accordance with the instant claimed invention.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants are submitting herewith a Declaration by inventor Frank Ko. Dr. Ko is an expert in advanced textile structures with special expertise in

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braiding technology. See paragraph 2 of Dr. Ko's Declaration outlining his extensive experience in this field.

In fact, as discussed in paragraph 4 of Dr. Ko's Declaration, he has direct experience with the prosthetic ligaments described in the primary reference, U.S. Patent 4,917,699. Dr. Ko assisted in the design of the braided polyester yarns used to prepare the prosthetic ligament described by Alan Chervitz in U.S. Patent 4,917,699 (see paragraph 4 of Dr. Ko's Declaration) and oversaw the Masters Thesis of his student Benny Soebroto wherein this permanent replacement prosthesis was characterized. As made clear by Dr. Ko in paragraph 4 of his Declaration, the intended purpose of the ligament prosthesis taught by Chervitz was for permanent replacement of the ligament. Accordingly, the Examiner's suggested substitution of the braided polyester yarns used by Chervitz with a degradable polymer such as taught by Wolowacz et al. (WO 95/01810 A1) would have altered the intended purpose and/or principle of operation of the permanent replacement ligament of Chervitz et al. Thus, such a combination is improper in accordance with MPEP 2143.01. Also see In re Gordon 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984) which held that if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there

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is no suggestion or motivation to make the proposed modification.

Further, as discussed in paragraph 3 of Dr. Ko's Declaration, the material from which a braid is made and microstructural design of a braid is recognized by those skilled in the art to provide a braid with unique properties which render such braids unobvious. Weaves prepared from different materials and/or with different microstructural designs have been acknowledged to be patentable over each other in similar arts such as vascular grafts. Those skilled in this art recognize that different weave architecture and braid geometry exhibit different properties altering their utility and/or applicability for various applications. See paragraph 3 of Dr. Ko's Declaration.

The ligament replacement construct of the instant invention is designed for regeneration of tissues. The material used for the three-dimensional braided construct was absorbable/biodegradable polymers. As discussed in paragraph 5 of Dr. Ko's Declaration, this fiber architecture provides for a variable microstructure for cell in-growth. As demonstrated in the experiments outlined in the specification at page 7, lines 9 through page 8, line 24, the fiber structure of the 3-dimensional braided scaffold of the present invention provided the scaffold with unexpectedly advantageous or superior properties with

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respect to cell ingrowth as compared to other scaffolds prepared from the same polymeric fibers. Specifically, fibroblasts organized along the length of the fibers and osteoblasts showed a distinctly different morphology as compared to fibroblasts with the 3-dimensional braided scaffolds of the present invention. In contrast, cell did not organize and morphology of cell types was not distinct in a microfiber, non-woven mesh scaffold prepared from the same biodegradable polymeric fibers. Also see paragraph 5 of Dr. Ko's Declaration.

MPEP 2144.09 is quite clear; a prima facie case of obviousness based upon structural similarity is rebuttable by proof that the claimed compounds possess unexpectedly advantageous or superior properties. Clearly the enhanced cell growth observed using 3-dimensional braided scaffolds of the present invention as compared to other scaffolds of the same material is an enhanced property not predicted or expected from the cited combination of prior art references, which is silent with respect to cell-ingrowth in three-dimensional braided scaffolds. Thus, any prima facie case of obviousness over the cited combination of references is rebutted by the experiments described at pages 7 and 8 of the instant application and discussed in Dr. Ko's Declaration at paragraph 5.

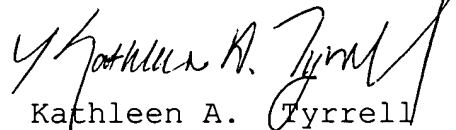
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Withdrawal of these rejections under 35 U.S.C. § 103(a)
is therefore respectfully requested.

Conclusion

Applicants believe that the foregoing comprises a full
and complete response to the Office Action of record.
Accordingly, favorable reconsideration and subsequent
allowance of the pending claims is earnestly solicited.

Respectfully submitted,


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